

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

APPLICATION FOR A VARIANCE FROM 21 CFR 1040.71(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE

Form Approved OMB No. 0914-0225
Expiration Date October 31, 2000
See Page 6 for GHS Statement
DOCKET NUMBER

NOTE: No laser light show, projection system, or device may vary from compliance with 21 CFR 1040.71(c) in design or use without the authority of this application in accordance with 21 CFR 1040.4.

INSTRUCTIONS

1. Check all applicable boxes and type or print the required information.
2. Sign in original and type (if typed).
3. NAME OF COMPANY
ZooBar, Inc.
4. MAIL YOUR APPLICATION TO THE DOCKETS MANAGEMENT BRANCH (HFA-305), FOOD AND DRUG ADMINISTRATION, 5600 FRIENDLY LANE, ROCKVILLE, MD 20852.
5. FILED DOCKETS PUBLICLY IF REQUESTED.

2. ADDRESS OF COMPANY (Include ZIP Code and P.O. Box if used. Include active street address also.)
75 West Chippewa St. Buffalo, NY 14202

3. NAME AND TITLE OF RESPONSIBLE PERSON
Mike Sherk, Owner/LSO

4. TELEPHONE NO. (include area code)
716/853-5555

5. DATE OF SUBMISSION
8/18/00

6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF **2** YEARS FROM THE DATE OF ISSUE (no longer than 4 years & limited to only two years if a temporary variance is requested). A REASONABLE FEE FOR MAINTENANCE IS PART OF THE VARIANCE.

7. PRODUCT DESCRIPTION AND USE
b. LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S)
ZooBar Laser Show Installation

b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED

- A laser display device
- A projector for a laser light show
- A laser light show
- Other (Specify) **per notification**

c. PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS

d. PRODUCT IS INTENDED FOR USE IN A

- Presentation or other static projection structure
- Theater
 - Standard auditorium or meeting room
 - Movie theater
 - Trade show or convention
 - Amphitheater or night club
 - Pavilion
 - Indoor arena
 - Outdoor arena
 - Museum
 - Other (Specify)

e. PRODUCT IS INTENDED TO BE USED

- At only one (1) location
- At a variety of (Total) locations
- Other (Specify)

f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION

- More than 15 days
- More than 5 but not more than 15 days
- Less than 5 days

g. TOUR IS INTENDED TO RUN FOR

- More than 6 months
- 1-6 months
- Less than one month
- Not applicable (Not a tour)
- Other (Specify)

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h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS

- Front screen projections
- Rear screen projections
- Holographic displays
- Multiple reflection/refraction effects
- Audience scanning (also includes scanning by audience uncontrolled arrays)
- Reflections from stationary mirrors or mirrored surfaces (Beam Mirrors)
- Stationary irradiation of rotating mirror discs, etc.
- Scanning irradiation of rotating mirror discs, etc.
- Fiber optic projections
- Fog smoke, or other scanning enhancement effects
- Other (Specify) **as per notification**

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LASER MEDIUM (e.g. Nd-YAG, CO ₂)	WAVE LENGTH(S) (nm)	PEAK POWER (watts)
Nd:YVO ₄	457, 532 nm	< 5 Watts
Diode Laser	645-850 nm	< 1 Watt
Argon/Krypton	455-850 nm	< 5 Watts

i. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND PULSE AND SCANNING FREQUENCY AND AMPLITUDE OF SCANNED bandwidth: from D.C. - 5 KH;
Modulation in both color and intensity: from D.C. - 100 KH

j. REASON FOR REQUESTING VARIANCE

- Compliance with the rules of 21 CFR 1040.71(c) would require the intended use of the product disclosed completely and limit the output power to the extent that the desired effects would not be satisfactorily visible
- Other or additional explanation (Specify)

DOV.1469

VAL.1

It is proposed to deviate from the provisions of 21 CFR 1040.11(c) in that the accessible emission levels would exceed the acceptable emission levels specified in 21 CFR 1040.11(a).

It is proposed to deviate from the provisions of 21 CFR 1040.11(c) as follows:

12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

Laser light shows and displays are accepted popular media in entertainment and the arts. Use of power levels in excess of the levels required by 21 CFR 1040.11(c) is necessary to achieve the required effects in these media.

Other or additional advantages (describe and explain):

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. Check at every point as apply. In item 14 'Remarks' justify why these are needed using additional words or necessary. State any other means of radiation protection that will be used.

a. All laser products, systems, shows, and projectiles will be certified to comply with 21 CFR 1040.10 and the operations of this variance and will be reported as required by 21 CFR 1040.10 AND 1040.11 using the reporting guides provided for such purpose. These actions will be accomplished prior to any introduction into commerce.

b. Effects not specifically indicated in this variance application will not be performed. No other effects will be added until an amendment to the variance has been obtained and the required reports or supplements, as applicable, have been submitted.

c. Scanning, projection, or reflection of laser and coherent radiation (laser show applications) into audience or other susceptible uncontaminated areas will not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target surfaces.

d. Laser radiation levels in excess of the limits of Class I will not be permitted at any point less than 3.0 meters above any surface upon which persons other than operators, performers, or employees are permitted to stand or 2.5 meters below or in direct separation from any place where such persons are permitted to be. Operators, performers and employees will not be required or allowed to view radiation above the limits of Class I or be exposed to radiation above the limits specified in 21 CFR 1040.11(c).

e. Any product which relies on scanning to avoid exposure, exposure, or produce class limits will incorporate a scanning regulated system which detects scanner start/stop motion and which will react fast enough to preclude exceeding the applicable limit.

f. All laser shows will be under the direct and personal control of trained, competent operator(s). The operator(s) will:

(1) Be an employee of the variance holder who will be responsible for the training and the conduct of the operator;

(2) Be located where all beam paths can be directly observed at all times; and

(3) Immediately terminate the emission of light show radiation in the event of any unsafe condition; or, for instant shows, upon request by any law enforcement officials.

g. The maximum laser projector output power will not exceed the level required to obtain the intended effects.

h. The projection system (i.e., the projector and all other components used to produce the lighting effects), will be securely mounted or immobilized to prevent unintended movement or repositioning. Beam masking will be provided as an integral part of the system design to prevent overexposure or exposure, beam stops, targets, etc.

i. Laser projectors will not be exhibited to any other party under an agreement of sale, lease, or loan unless and until the recipient demonstrates that they have a variance in effect at the time of delivery that permits them to produce laser light shows incorporating such projector(s).

j. In addition to the requirements of 21 CFR 1040.10(h), the manufacturer of laser projection systems will provide to parties who purchase, lease, or borrow the equipment, adequate users' instructions for safe installation and operation which expand the responsibility of the recipient as an independent light show manufacturer to fulfill the required reports and apply for and obtain a variance from FDA prior to introduction into commerce of any laser light shows.

k. The requirements of 21 CFR 1040.30(a)(1) and (2) will be accomplished through the use of written procedures for setup, alignment, removal, and performance of each show. These procedures will be in sufficient detail to ensure compliance with 21 CFR 1040.10 (the conditions of this variance, and the control of access to radiation areas using the procedures described in the ANSI/Z136.1 standard for the safe use of lasers (American National Standard for Safe Use of Lasers, 1-900 Broadway, New York, NY 10036) or any other equivalent user consensus standard and, where applicable, state or local requirements. Laser radiation areas which can expose radiation levels above the limits specified in 21 CFR 1040.11(c) will be clearly identified by the posting of warning signs and/or restricting access through physical means (such as pressure限制器, gates, cables, barriers, guards, etc.). These requirements apply to temporary areas (such as during set up and alignment procedures and to final or permanent areas). The variance holder will retain the records of these procedures and the results of all tests as required by 21 CFR 1040.31. A copy of the variance application, the approved letter, current procedures, and records relating to each particular show will be with the operator or other responsible individual and will be made available for inspection by FDA and other responsible authorities.

Aug-22-00 13:03 From-

1. All resource warning notification will be made as early as possible to appropriate Federal, state, and local authorities preceding show activity with dates and locations clearly and completely identifying and a brief description of the proposed effects producing a statement of the maximum power output intended. Such notifications will be made, but are necessary for limited, etc.

- (1) The Center for Devices and Radiological Health, Office of Compliance (HFZ-342), 2020 Gaithers Road, Rockville, MD 20850, providing the initial and closing dates for laser installations and the itinerary for mobile effects. In addition, unless all impacts of each show have been reported and application numbers clearly referenced, each notice will include detailed descriptions of each show and a listing of all effects to be performed in sufficient detail to confirm compliance with the regulations and fire variance.
- (2) The Federal Aviation Administration (FAA) for any projections into open airspace at any time (i.e. including set up, alignment rehearsals, performances, etc.). If the FAA objects to any laser effects, the objectives will be rescored and any conditions requested by FAA will be adhered to. If these conditions cannot be met, the disfavored effects will be deleted from the show.
- (3) State and local aviation control offices/applications for all shows to be performed within their jurisdictions. All requirements of state and local law will be satisfied and any objections raised by local authorities will be responded to the effects deleted (A list of federal and state liability as available from the Center for Devices and Radiological Health upon request.)

14. REMARKS

ZooBar will only use certified equipment from companies manufacturing certified projectors or laser effects. From time to time, rental equipment may be necessary. In this event, ZooBar will only rent from companies with proper variances to do so. (i.e. - Las Vegas Lasers and/or certified projectors manufactured by ZooBar and/or manufacturers certified in accordance with FDA/CDRH 21 CFR 1040.10 and 1040.11)

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete, and correct to the best of my knowledge and understanding; that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading or incorrect in any manner. I have submitted and will submit all reports required by 21 CFR 1002.10 and 1002.11 on the laser equipment and sources. I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health to supply other information as may be necessary to evaluate and act on this application.

16. SIGNATURE

16. NAME (Type or Print)

Mike Sherk

17. TITLE

Owner/LSO